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**For registration proposal and translation
in the Scientific Centre of Drug and Medical Technology
Expertise of Armenia**

INSTRUCTIONS
for the medical use of the drug

Mastodynon®

A complex homeopathic medication

Registration number:

Trade name of the drug: MASTODYNON®

Pharmaceutical form: Homeopathic tablets

COMPOSITION

1 tablet contains:

Agnus castus Ø (Lilac chaste tree or monk's pepper tree)
162.0 mg

Caulophyllum thalictroides D4 (Blue cohosh)	81.0 mg
Cyclamen D4 (European cyclamen)	81.0 mg
Ignatia D6 (Strychnos Ignatia)	81.0 mg
Iris D2 (Iris versicolor)	162.0 mg
Lilium tigrinum D3 (Tiger lily)	81.0 mg

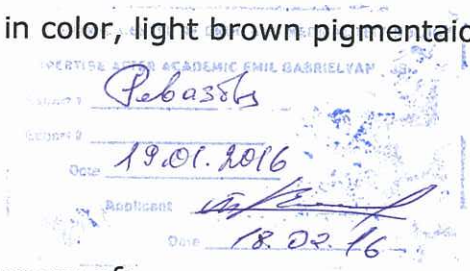
Excipients: lactose monohydrate, potato starch, magnesium stearate.

DESCRIPTION

Round tablets, flat cylindrical in shape, beige in color, light brown pigmentation might be possible.

PHARMACOTHERAPEUTIC GROUP

Homeopathic medication



THERAPEUTIC INDICATIONS

For symptomatic treatment in the complex therapy of:

- premenstrual syndrome (cyclic mastodynia, breast tension, mental lability, constipation, edemas, headache/migraine)
- mastopathy
- menstrual cycle disorders

CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the excipients of the medicinal product.



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SCIENTIFIC CENTRE FOR DRUG AND MEDICAL DEVICE RESEARCH
EXPERTISE AFTER ACADEMIC EMIL GABRIELTAN
Expert 1 *Pebaraly*
Expert 2
Date *19.01.2015*
Applicant *[Signature]*
Date *18.02.16*

METHOD OF ADMINISTRATION AND DOSAGE

Take 1 tablet internally twice a day with a small amount of liquid.

Mastodynon® should be taken for at least 3 months, including during menstrual bleeding.

Improvement generally begins in 6 weeks. If symptoms return after the medication is discontinued, consult your physician. Because the medication is well-tolerated, it is suitable for long-term treatment.

If you took more Mastodynon tablets than you should:

If big amounts of the medicinal product are taken, gastrointestinal complaints or diarrhoea may occur in patients suffering from lactose intolerance. Stop taking the medicine and tell your doctor.

If you forgot to take Mastodynon tablets:

Do not take a double dose to make up for a forgotten dose.

If you stop taking Mastodynon tablets:

Consult your doctor or pharmacist after you have stopped treatment.

If you have any further questions on the use of the product, ask your doctor or pharmacist.

SIDE EFFECTS

Severe allergic reactions with face swelling, dyspnoea and swallowing difficulties. (Allergic) skin reactions (rash and urticaria), headache, dizziness, gastrointestinal disorders (such as nausea, abdominal pain), acne, menstrual disorders have been reported. The frequency is not known. At the first signs of a hypersensitivity / allergic reaction Mastodynon tablets must not be taken again. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

DRUG INTERACTIONS

Because of the possible dopaminergic and oestrogenic effects of Vitex agnus castus, fructus interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.

PREGNANCY AND BREAST-FEEDING

Ask your doctor or pharmacist for advice before taking any medicine.

There is no indication for the use during pregnancy.

Data from reproductive studies suggest that extracts of Vitex agnus castus, fructus may affect lactation.

Mastodynon tablets must not be taken during pregnancy and lactation.

SPECIAL INSTRUCTIONS

Smoking and drinking alcohol has a negative effect on the efficacy of homeopathic medications. For long-term, vague, or recurrent symptoms, consult a doctor, since the issue may be a disease that requires treatment under a doctor's supervision.

If you suffer or suffered from an oestrogen-sensitive cancer consult your doctor before using medicinal products containing Vitex agnus castus.



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If you are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens consult your doctor before using medicinal products containing Vitex agnus castus.

The use in children under the age of 12 years has not been established due to lack of adequate data.

Vitex agnus castus fructus is thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult a doctor before use.

In cases of prolactin secreting tumours of the pituitary gland the intake of medicinal products containing Vitex agnus castus fructus can mask the symptoms of the tumour.

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

DOSAGE FORM

Twenty tablets in each blister pack. Three or six blister packs, along with instructions for use, are enclosed in a cardboard package.

STORAGE CONDITIONS

Store below 25°C in a dry place protected from light and out of the reach of children.

SHELF LIFE

3 years.

Do not use the medication after the expiry date indicated on the package.

CONDITIONS OF SALE AT PHARMACIES

Rx. With medical prescription.

MANUFACTURER

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Date	<i>19.01.2016</i>
Applicant	<i>[Signature]</i>
Date	<i>18.02.16</i>

Neumarkt, 03 July 2014

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ppa Dr. Bernd Roether
Head Division DRA

